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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/625,558   | 07/24/2003  | Francesca Benedini   | 026220-00038        | 8114             |
| 4372   | 7590        | 02/07/2006           | EXAMINER            |                  |
| ARENT FOX PLLC<br>1050 CONNECTICUT AVENUE, N.W.<br>SUITE 400<br>WASHINGTON, DC 20036 |             |                      | SACKEY, EBENEZER O  |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1626                |                  |

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/625,558 | <b>Applicant(s)</b><br>BENEDINI ET AL. |  |
|                              | <b>Examiner</b><br>EBENEZER SACEY    | <b>Art Unit</b><br>1626                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 November 2005.  
 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6 and 7 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 6 and 7 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☒ Certified copies of the priority documents have been received in Application No. 10/031,412.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of Claims**

Claims 6 and 7 are pending.

This is in response to applicant's amendment filed 11/09/05.

Claims 6 and 7 have been amended.

### **Claim Rejections - 35 U.S.C. § 103**

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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3. Claims 6 and 7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Soldato (U.S. Patent number 5,700,947) ('947') for the reasons set forth in the office action mailed on 08/11/05.

***Response to Amendment***

Applicant's arguments filed 11/09/05 have been fully considered but they are not deemed persuasive. Applicants argue that Soldato does not teach or suggest the "4-nitroxybutyl ester of 2-(6-methoxy-2-naphthyl)-propionic acid having the enantiomeric excess of the (S) form higher than or equal to 97%". Contrary to applicant's arguments, Soldato discloses the racemate, which includes the (S) form. In response, a purer form of a known compound is not patentable over the known compound. Applicants next argue that tests carried out by applicants have shown that the prior process of preparing the compounds do not allow naproxene nitroxyalkylesters having an enantiomeric excess in the range of 55-80% only with a specific organic base. This argument is not germane to the instant invention because the claims are drawn to "4-nitroxybutyl ester of 2-(6-methoxy-2-naphthyl)-propionic acid compounds having the enantiomeric excess of the (S) form higher than or equal to 97% or 98%" respectively not to a process of preparing the said compounds. It appears the novelty of this application resides in the process of preparing 4-nitroxybutyl ester of 2-(6-methoxy-2-naphthyl)-propionic acid compounds having the claimed enantiomeric excess of the (S) form higher than or equal to 97% or 98%" not the compound itself.

For the reasons of record, claims 6 and 7 remain rejected as previously stated.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

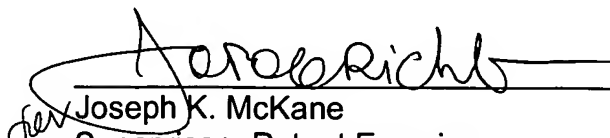
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

EOS  
February 3, 2006

  
Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626, Group 1600

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